Supreme Court, U.S.
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No. 10-332

IN THE

Supreme Court of the United States

MICHAEL J. MCGUAN AND LILLIAN JOHNSON,

Petitioners,

v.

ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIOVASCULAR SYSTEMS, INC., AND ORIGIN MEDSYSTEMS, INC.,

Respondents.

On Petition for a Writ of Certiorari to the California Court of Appeal Sixth Appellate District

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Are Petitioners' fraud-on-the-FDA claims seeking to negate the preemptive effect of FDA's re-approval of the Ancure device based on Respondents' alleged failure to provide different or additional information to FDA during the re-approval process preempted under *Buckman*?

2. Does this Court have jurisdiction to review a state trial court's denial of Petitioners' motions to amend their complaints to add claims for fraud-on-the-FDA when that decision was affirmed on appeal on the adequate and independent ground that Petitioners waived this argument by violating Cal. Rule of Court 8.204(a)(1)(B)?

PARTIES TO THE PROCEEDING

The California Court of Appeal for the Sixth District ordered the appeals in *Michael J. McGuan v. Endovascular Technologies, Inc., Guidant Corporation, Advanced Cardiovascular Systems, Inc., and Origin Medsystems*, and *Lillian Johnson v. Endovascular Technologies, Inc.*, to be considered together for briefing, oral argument, and decision. The California Court of Appeal issued one decision on both appeals.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Respondents Endovascular Technologies, Inc., Guidant Corporation, and Origin Medsystems, Inc., are wholly owned subsidiaries of Boston Scientific Corporation.

Respondent Advanced Cardiovascular Systems, Inc., is a wholly owned subsidiary of Abbott Labs, Inc.

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BRIEF IN OPPOSITION

STATEMENT OF THE CASE

Petitioners seek review of a decision by the California Court of Appeal for the Sixth Appellate District (Sixth District) (i) affirming the grant of summary judgment in their product liability actions involving the ANCURE® ENDOGRAFT® System (Ancure device), a Class III medical device; (ii) finding Petitioners' fraud-on-the-FDA claims preempted after assuming "for purposes of argument" that Petitioners "have, or could have" stated such claims; and (iii) finding that by failing to comply with a well-settled state procedural requirement, Petitioners had "waived" their

arguments that the trial court erred in denying their motions to amend to their complaints.

Background

The Ancure device was first approved for commercial distribution by the federal Food & Drug Administration (FDA) in September 1999 pursuant to a Pre-Market Approval (PMA) Application. (Pet. App. 4.) Approximately one year and a half later, Respondents learned of issues with their Medical Device Reporting and Quality System Regulation compliance. Respondents investigated these issues and reported them to FDA. (Pet. App. 5-6.) The Ancure device was temporarily recalled for a five-month period from March 16 to August 17, 2001. (*Id.*) Respondents submitted PMA Supplements to address the regulatory deficiencies that prompted the recall. (Pet. App. 6.) On August 17, 2001, FDA re-approved the Ancure device finding that Respondents PMA Supplements satisfyed the standards for commercial distribution. (Pet. App. 6.)

Both Petitioners underwent surgery with Ancure devices after FDA's re-approval in August 2001. (Pet. App. 8.) Both Petitioners allege they suffered complications from the Ancure surgeries. (Pet. App. 8-9.)

Because Petitioners studiously conflate arguments supporting the viability of the claims that were alleged in the complaints (and that were the subject of the trial court's summary judgment ruling), with those supporting the claims that were alleged in Petitioners' proposed amended complaints, it is necessary to discuss the proceedings below in some detail.

The Operative Complaints

Petitioner McGuan's original complaint that was the subject of the trial court's and the Sixth District's decisions alleged eight causes of action: (1) Strict Product Liability (Failure to Warn); (2) Strict Product Liability (Pursuant to Restatement (Second) of Torts § 402A (1965)); (3) Negligence; (4) Breach of Express Warranty; (5) Breach of Implied Warranty; (6) Fraudulent Concealment; (7) Punitive Damages; and (8) Violations of the Consumer Legal Remedies Act. (Pet. App. 8.)

Petitioner Johnson's First Amended Complaint that was the subject of the trial court's and the Sixth District's decisions alleged the same eight causes of action, and included a ninth claim for "fraud and misrepresentation." (Pet. App. 8.)

Critically, neither complaint alleged that Respondents violated any FDA regulations. (Pet. App. 9.)

Respondents' Motions for Summary Judgment

Respondents moved for summary judgment arguing that Petitioners' claims were preempted by section 360k(a) of the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, because they had surgery after FDA had reviewed Respondents' PMA Supplements and re-approved the Ancure device. (Pet. App. 8-9.)

Petitioners claimed that preemption should not apply because Respondents had obtained the re-approval through "fraud-on-the-FDA." (Pet. App. 9.) As Petitioners acknowledged in their opposition pa-

pers in the trial court, no claims for fraud-on-the-FDA were alleged in their complaints, however, they intended to file motions to amend their complaints to add these claims in the future. (Sixth District APP 0955-56 ("Both plaintiffs will also shortly move to add fraud on the FDA causes of action to their complaints").) Petitioners further acknowledged that although "fraud-on-the-FDA" claims are generally preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), their claims should be allowed to proceed because in this case FDA "took strong action" against Respondents. (Pet. App. 18.)

The trial court granted Respondents summary judgment on all of Petitioners' claims. (Pet. App. 34, 43.) As the trial court explained, claims that Respondents should have conducted different or additional testing on the Ancure device, or should have provided different or additional warnings with the device, would impose "additional requirements" to those required by FDA. (Pet. App. 31, 40.) Relying on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the trial court held that such "requirements" were preempted by section 360k(a) of the MDA because the Ancure device had been approved and then re-approved by FDA through the PMA process before Petitioners were treated with the device. (Pet. App. 31, 40.)

The trial court also rejected Petitioners' argument that Respondents had engaged in "fraud-on-the-FDA" because this Court has held that such claims are preempted. *Buckman*, 531 U.S. at 341. As the trial court explained:

> While [Petitioner] argues that he should be permitted to proceed on claims that are premised on fraud on the FDA, cit-

> ing the Stevens concurrence in *Buckman (supra)*, [Petitioner] neither pleads such in his complaint relating to the approval nor presents any evidence that would establish there was any fraud on the FDA that affected the pre-approval process that preceded the surgery and implantation of the device; nor does he plead or present evidence that the FDA withdrew its approval and ordered the device off the market. To the contrary, Defendants present evidence that the FDA never removed the ANCURE System from the market, but rather on August 17, 2001, it re-approved the system. [Petitioner] provides no evidence showing otherwise.

(Pet. App. 33 and 42.)

Petitioners' Motions to Amend

After Petitioners filed their opposition papers to the motions for summary judgment, and after Respondents filed their reply briefs, Petitioners moved for leave to amend their complaints to add new causes of action for "fraud on the FDA." (Pet. App. 21-22.)

Petitioners now seek to recast their proposed causes of action for fraud-on-the-FDA as "parallel claims" based on Respondents' alleged fraud on "patients and their physicians." (Pet. 14 ("[t]he trial court denied petitioners' motions to amend their complaints, rejecting petitioners' parallel exception argument pertaining to fraud on petitioners and their physicians"); *see id.* at Question Presented No. 2, pp.

4, 5, 13, 14, 16, 18, 21, and 25.) However, Petitioners' new "fraud on patients and physicians" argument was not presented to the trial court and was not raised in the Sixth District until Petitioners' reply briefs.

Instead, at the trial court Petitioners argued for the viability of their proposed fraud-on-the-FDA causes of action by urging the trial court to create an exception to this Court's holding in *Buckman*. (Sixth District APP 2268-90; *see id.* at 2277 ("Defendants' Fraudulent Conduct Resulted in the Reapproval of Ancure in 2001"); *id.* at 2278 ("*Buckman* Does Not Control the Outcome of this Case").) Although Petitioners' proposed causes of action for fraud-on-the-FDA used the words "patients and their physicians," Petitioners made absolutely no argument to the trial court that *Buckman* should not control because they were really seeking to add fraud claims that only happened to mention Respondents' alleged fraud-on-the-FDA. (Sixth District APP 2268-90.)

Respondents opposed the motion because fraud-on-the-FDA claims are plainly preempted under *Buckman*, and amendment therefore would be futile. (Pet. App. 9.) The trial court denied Petitioners' motions to amend. (Pet. App. 9.)

The Appeal to the Sixth District[1]

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[1] The Sixth District affirmed the trial court's grant of summary judgment on Petitioners' claims for strict product liability, negligence, breach of express warranty, breach of implied warranty, and violations of the Consumer Legal Remedies Act, finding these claims preempted under section 360k(a) of the MDA. (Pet. App. 14.) Petitioners do not appear to contest the Sixth District's decision with respect to these claims.

On appeal, Petitioners continued to argue that FDA's re-approval of the Ancure device should not preempt their state law claims because the re-approval was obtained by fraud-on-the-FDA. In fact, Petitioners' opening brief to the Sixth District identified the "main issue" on appeal as whether preemption should apply when "re-approval for the device was obtained by [Respondents'] fraud on the FDA, proven by the FDA with severe consequences on [Respondents]" (Pet. App. 14 n.6 (quoting Petitioners' opening brief).) Petitioners further acknowledged that their "claims all stem from the fraudulent conduct of [Respondents] during 2001 in the context of the recall and reapproval of Ancure" (*Id.*) The Sixth District characterized Petitioners' arguments as follows:

> [Petitioners] attempt to distinguish the present case from *Buckman* on the ground that the "FDA had not investigated the Buckman defendant for any alleged wrongdoing." They point out that "the FDA took strong action against" [Respondents] and that Justice Stevens's concurring opinion in *Buckman* is "an invitation, as it were, to bring a case involving fraud 'policed' by the FDA."

(Pet. App. 18.)

The Sixth District first examined the allegations in both operative complaints to determine whether either Petitioner had actually alleged a cause of action for fraud-on-the-FDA. (Pet. App. 15-16.) In the end, the court noted, "[f]or purposes of argument, we will assume that plaintiffs have, or could have, stated

causes of action for fraud on the FDA." (Pet. App. 16.) After discussing the holding in *Buckman*, the Sixth District found that Petitioners' "assumed" causes of action for fraud-on-the-FDA were pre-empted because

> [t]hough defendants were prosecuted and entered into a plea agreement for fraudulent conduct that occurred before March 2001, the FDA took no action against defendants for their conduct in seeking reapproval in August 2001. Instead, the FDA continued to allow the Ancure Device to be marketed, and even approved a premarket approval supplement in April 2002. Since the FDA failed to take action against defendants for any alleged fraudulent conduct after March 2001, *Buckman* is controlling. Accordingly, plaintiffs' state law tort claims for fraud on the FDA are pre-empted by federal law.

(Pet. App. 18-19.)

Although Petitioners did not raise the issue until their reply briefs, the Sixth District also addressed whether the inclusion of allegations of "fraud on patients and their physicians" could save Petitioners' proposed causes of action:

> Those same principles apply with equal force to claims involving defendants' misrepresentations to plaintiffs and their physicians after March 2001. It is undisputed that the FDA found no violations of federal regulations after March

> 2001. Thus, if plaintiffs were allowed to proceed with their state law fraud claims, a finding of liability would also "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (*Buckman*, at p. 350.)

(Pet. App. at 19-20.)

Finally, although Petitioners challenged the denial of their motions to amend on appeal to the Sixth District, their opening briefs failed to include any argument or legal authority to support a reversal of the trial court's decisions. (Pet. App. 21-22.) Instead, Petitioners "purport[ed] to incorporate by reference the same authorities and arguments submitted to support their motions in the trial court." (Pet. App. 21.)

The Sixth District held that this "incorporation by reference" was improper under California Rule of Court 8.204(a)(1)(B), and numerous reported decisions prohibiting the "incorporation by reference" in appellate briefs. (*Id.*) Consequently, the Sixth District found that Petitioners had "waived" their claims that the trial court erred in denying their motions to amend.[2] (Pet. App. 22.)

REASONS FOR DENYING THE WRIT

I. THE SIXTH DISTRICT CORRECTLY FOUND THAT PETITIONERS' "ASSUMED" CAUSES OF ACTION FOR FRAUD-ON-THE-FDA WERE PREEMPTED

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[2] Nevertheless, the Sixth District went on to address Petitioners' arguments and found them without merit. (Pet. App. 22 ("In any event, plaintiffs' contentions have no merit.").)

As explained above, it is doubtful whether either of Petitioners' operative complaints included a cause of action for fraud-on-the-FDA. Petitioners certainly did not think so, or they would not have moved to amend their complaints to add such a claim, nor would they have attempted to appeal the denial of their motions to amend. Moreover, Petitioners continue to argue here for the supposed viability to their "proposed" cause of action. (Pet. 4, 14, 20, and 23.) Nevertheless, the Sixth District "assumed" "for purposes of argument" that Petitioners had, or could have, stated such a claim, and ruled that such a claim would be preempted. (Pet. App. 16.) This decision is correct.

Whether the cause of action is evaluated based on allegations cobbled together in the operative complaints, or on allegations in the proposed amended complaints, or whether the cause of action is called fraud-on-the-FDA or a "parallel claim," the result is the same. Petitioners sought to undermine the preemptive effect of FDA's re-approval of the Ancure device based on Respondents' alleged failure to provide different or additional information to FDA during the re-approval process.

Petitioners' proposed cause of action alleged that Respondents made misrepresentations about the Ancure device's safety data "*with the intention that the FDA would rely on them in 2001, in deciding to allow the device to continue being implanted in patients, in deciding whether to allow the device to go through a re-approval process after Guidant recalled the device, and in deciding to allow the device to be re-approved.*" (Pet. App. 70 (emphasis added).) Petitioners further sought to allege that "*[h]ad the FDA ...been aware of*

the true facts, the device would have been disapproved by the FDA." (*Id.* at 70-71.) These are classic fraud-on-the-FDA allegations, precisely the sort of allegations that *Buckman* found preempted.

The plaintiffs in *Buckman* claimed that a medical device manufacturer of bone screws used for spinal surgery had made fraudulent misrepresentations to FDA in order to obtain approval to market the devices. *Buckman*, 531 U.S. at 346-47. The state-law claims at issue in *Buckman* were described by this Court as follows:

> Plaintiffs say petitioner made fraudulent representations to the [FDA] in the course of obtaining approval to market the [device]. Plaintiffs further claim that such representations were at least a "but for" cause of injuries that plaintiffs sustained from the implantation of these devices: Had the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured.... We hold that such claims are preempted by the Federal Food, Drug, and Cosmetic Act.

Buckman, 531 U.S. at 343-44.

As noted in *Buckman*, FDA's review processes are governed by a "comprehensive scheme for determining whether an applicant has demonstrated that a product" meets the requirements for approval. 531 U.S. at 348 (discussing the § 510(k) process and noting that the PMA process is even more rigorous); *see also Riegel*, 552 U.S. at 317-19 (describing PMA process). Based on the comprehensiveness of that regula-

tory scheme, as well as the necessity for FDA to exercise expertise and discretion in determining what information is necessary to support PMA approval, this Court found preempted precisely the type of claims Petitioners sought to add here: those premised on the contention that FDA was defrauded because it did not request, or the manufacturer did not supply, some additional or different piece of information. *Buckman*, 531 U.S. at 350-51 (noting that allowance of such claims would cause manufacturers to "submit a deluge of information that the Administration neither wants nor needs").

This ruling has been followed consistently in the lower courts whether the plaintiff refers to such a claim as "fraud-on-the-FDA" or as a "parallel claim" under *Riegel*. *See e.g.*, *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) (finding "Gomez's state-law claims related to Kendall's alleged failure to provide information obtained after the FDA approved the Angio-Seal risk the same interference with the federal regulatory scheme . . . and are pre-empted."); *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008) (finding claim that manufacturer did not "fully and honestly disclose to the FDA all potential risks" during PMA process preempted under *Buckman*); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559 at *8 (M.D.N.C. Aug. 5, 2009) (holding that "any claims which are based upon an alleged breach of an FDA disclosure requirement, while not necessarily expressly pre-empted, are impliedly pre-empted"); *Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226, 1231 (D. Nev. 2009) (construing scope of parallel claims under *Riegel* and holding that "any claim by [plaintiff] based on a contention that DePuy Spine provided inaccurate or in-

complete information to the FDA would be preempted due to the inherent interference of such allegations with the FDA's authority and its administration of federal law under the implied preemption principles stated in [*Buckman*]"); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (discussing scope of parallel claims under *Reigel* and holding that "a state-law claim that the defendant made misrepresentations to the FDA is preempted because such a claim would not exist absent federal regulatory scheme established by the FDCA [Food Drug & Cosmetic Act]"); *Link v. Zimmer Holdings Inc.*, 604 F. Supp. 2d 1174, 1179 (N.D. Ill. 2008) (holding that "any allegations that Zimmer committed fraud upon the FDA are also preempted and therefore cannot provide the basis for Link's claims" where plaintiff argued "that the *Riegel* analysis should not apply because Zimmer did not fully and honestly disclose all information relevant to the safety of the [device] to the FDA").

In sum, Petitioners cannot avoid preemption by re-characterizing their proposed fraud-on-the-FDA claim as a "parallel claim" because the Sixth District correctly found that alleged violations of FDA disclosure requirements are impliedly preempted under *Buckman*.

II. THE DECISION OF THE SIXTH DISTRICT DOES NOT CREATE A CONFLICT UNDER RULE 10

Petitioners have failed to identify any decision of another state court of last resort, or of a United States court of appeals, that conflicts with the decision of the Sixth District.

Instead, Petitioners cite two district court opinions, and one from the California Supreme Court in an attempt to manufacture a conflict. (Pet. 21, 26, and 28.) As an initial matter, even if there were a conflict between the Sixth District's decision and the cases cited by Petitioners, that would not provide a basis for granting certiorari under the criteria set out in Rule 10(a), because the conflict would be between an intermediate state court and two district courts, or between decisions of appellate courts of differing levels in the same state.

Furthermore, there is no conflict. Petitioners cite *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802 (W.D. Va. 2002), and *Wawrzynek v. Statprobe, Inc.*, No. 05-1342, 2007 WL 3146792 (E.D. Pa. Oct. 25, 2007), however these cases arise from the same criminal investigation in which FDA had affirmatively found fraud and removed the device from the market. Here, the Ancure devices implanted in Petitioners had been re-approved by FDA based on PMA Supplements submitted after March 2001. And, as the Sixth District noted, "[t]hough defendants were prosecuted and entered into a plea agreement for fraudulent conduct that occurred before March 2001, the FDA took no action against defendants for their conduct in seeking reapproval in August 2001. Instead, the FDA continued to allow the Ancure Device to be marketed, and even approved a premarket approval supplement in April 2002." (Pet. App. 18.)

The other case cited in the Petition, *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077 (2008), *cert. den. sub nom, Albertson's Inc. v. Kanter*, 129 S. Ct. 896 (2009), involved the question of whether a state law claim for violation of a specific section of the Nu-

trition Labeling and Education Act (NLEA), was impliedly preempted by section 337 of the FDCA. *Id.* at 1085. Although section 337 requires all proceedings for the enforcement of the FDCA to be brought by the United States, section 343-1 of the NLEA expressly preempts only those state law labeling requirements that are "not identical to the requirement" set out in NLEA. *Farm Raised Salmon*, 42 Cal. 4th at 1086 (internal quotation and emphasis omitted). The California Supreme Court found that "[t]he words of section 343-1 clearly and unmistakably evince Congress's intent to authorize states to establish laws that are 'identical to' federal law." *Id.* at 1090. There is no such explicit limitation on the reach of preemption here. Moreover, as noted repeatedly above, Petitioners' complaints do not allege violations of any federal regulatory requirements—much less federal regulatory requirements identical to Petitioners' state causes of action. In short, there is no conflict between the Sixth District's decision finding Petitioners' fraud-on-the-FDA claims preempted and *Farm Raised Salmon's* interpretation of a specific preemption limiting provision in the NLEA.

III. THE SIXTH DISTRICT'S DECISION AFFIRMING THE DENIAL OF PETITIONERS' MOTIONS TO AMEND IS SUPPORTED BY ADEQUATE AND INDEPENDENT STATE LAW

The Sixth District affirmed the trial court's denial of Petitioners' motions to amend their complaints on the adequate and independent ground that Petitioners had waived this argument under well-settled state procedural rules. The Sixth District stated:

> Plaintiffs next contend that the trial court erred in denying their motions to

amend their complaints. They purport to incorporate by reference the same authorities and arguments submitted to support their motions in the trial court.

California Rules of Court, rule 8.204(a)(1)(B) requires that appellate briefs "support each point by argument and, if possible, by citation of authority." "It is well settled that the Court of Appeal does not permit incorporation by reference of documents filed in the trial court. (*Colores v. Board of Trustees* (2003) 105 Cal.App.4th 1293, 1301, fn.2 [130 Cal.Rptr.2d 347] ['[I]t is not appropriate to incorporate by reference, into a brief, points and authorities contained in trial court papers, even if such papers are made a part of the appellate record']. . . .)" (*Soukup v. Law Offices of Herbert Hafif* (2006) 39 Cal.4th 260, 294, fn.20 [46 Cal.Rptr.3d 638, 139 P.3d 30].) A Court of Appeal may refuse to consider arguments incorporated by reference. (*Parker v. Wolters Kluwer United States, Inc.* (2007) 149 Cal.App.4th 285, 290-291 [57 Cal.Rptr.3d 18] (*Parker*).) Thus, we have not considered these arguments. Since plaintiffs have failed to submit any other arguments or authorities, the issue has been waived.

(Pet. App. 21-22.)

The "[f]ailure to present a federal question in conformance with state procedure constitutes an adequate and independent ground of decision barring review in this Court, so long as the State has a legitimate interest in enforcing its procedural rule." *Michigan v. Tyler*, 436 U.S. 499, 512 n.7 (1978); *see also Jimmy Swaggart Ministries v. Bd. of Equalization of California*, 493 U.S. 378, 398 (1990) (the "unambiguous application of state procedural law makes it unnecessary for us to review the asserted claim"); *Michigan v. Long*, 463 U.S. 1032, 1041-42 (1983).

The majority of Petitioners' arguments for certiorari are based on the supposed viability and "great importance" of the issues purportedly implicated by their proposed amended complaints. However, because the trial court's denial of Petitioners' motions to amend is supported by an adequate and independent state law ground, the only issues that remain are squarely addressed by this Court's decision in *Reigel*.

CONCLUSION

For the reasons stated above the Petition should be denied.

Respectfully submitted.

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